STATEMENT UNDER ARTICLE 19

The present invention relates to controlled release compositions of β-lactam antibiotic agent namely cephalosporins and at least two carbomers.

XP 002278979 cited in the International Search Report as category citation teaches enteric-coated cefaclor micro granules prepared by extrusion and airflow coating method. This composition is suitable for twice daily administration and is delayed release type.

US 3,074,852 also cited in the International Search Report teaches sustained release formulations utilizing a particular grade of carbopol-934. This polymer characteristically provides a zero order release profile of the active ingredient. However, for the cephalosporins, which are preferably absorbed from the proximal part of GIT, carbopol 934 would not be suitable.

In addition, the cited prior art defines drug to polymer ratio to be at least 1:0.5. Such ratio may not be applicable to the present invention, where the drug to polymer ratio is about 1:0.35.

The present application is directed towards use of at least two carbomers namely combination of Carbopol 971P and Carbopol 974P which produces a semi enteric effect, whereas Carbopol 974P, on the other hand, provides a prolonged linear release profile.

US 3,639,560 cited in International Search Report discloses the invention, which is primarily applicable in the dry period therapy in the treatment and control of bovine mastitis. Column 3, line 4 discloses various therapeutic agents used in the above invention. Column 4, column 5, example 4 discloses dispersion of sustained release formulation in 0.5% w/v carbopol 934 aqueous vehicle.

In contrast to the above US patent '560, which defines intra-mammary injectable dosage form of active substance, the present formulation is for oral administration in the form of tablets.

Further, Carbopol is only a suspension aid in '560, whereas combination of carbomers namely carbopol 971P and 974P are used as release modifying agent in the present invention.

WO 2004/019901 cited in the International Search Report under "E" category was published later than the filing of the present application and does not require comments.

As stated above, it is clear that none of the cited art alone or in combination teaches the present invention. There is no motivation in the cited art that controlled release type composition comprising cephalosporin and at least two defined carbomers may be formed. The present inventors have found that combination of the specified carbopols are capable for providing the control of the release of active ingredient. Taking cue from the cited art it would not be possible to combine the carbopol 971 and 974 along with cephalosporin to provide a pharmaceutical composition for controlled drug delivery wherein combination of the Carbopol 971P and Carbopol 974P can be manipulated to achieve the desired drug release profile suitable for the specific needs of cephalosporins. Further, the specific polymer to drug ratio of the present invention is also not taught or motivated from the cited art.

To emphasize the above distinguishing features the applicant wishes to amend the claims based on the description which may please be taken as amendment under Article 19.